CLAIMS:

1. A gastrointestinal lead adapted to be implanted within the body to conduct electrical stimulation from an implantable or external gastrointestinal stimulator to a site of the GI tract and to conduct electrical signals of the GI tract from the site to the implantable or external gastrointestinal stimulator comprising:

an elongated lead body comprising a common lead body trunk extending from a lead body trunk proximal end to a junction with a plurality of lead body legs that extend from the junction to a like plurality of lead body leg distal ends;

an electrode head formed at each lead body leg distal end having a plate and supporting at least one stimulation/sense electrode and an active fixation mechanism whereby a plurality of active fixation attachment mechanisms are supported by a plurality of electrode heads;

a connector assembly at the lead body proximal end comprising a plurality of connector elements; and

a plurality of lead conductors enclosed within the lead body, each lead conductor extending between a stimulation/sense electrode through a lead body leg and the lead body trunk to a proximal connector element of the connector assembly,

wherein each active fixation mechanism extends away from the plate of the electrode head and is shaped to penetrate through the serosa and into the muscularis externa upon application of force to the electrode head to draw the plate against the serosa and operatively contact the stimulation/sense electrode with the GI tract wall, whereby the plate inhibits further advancement of the active fixation mechanism and perforation of the GI tract wall and the active fixation mechanism inhibits dislodgement of the stimulation/sense electrode from operative contact with the GI tract wall;

2. The gastrointestinal lead of Claim 1, wherein;

one active fixation mechanism comprises a helix comprising one or more coil turn extending from a helix fixed end and a helix free end and having a helix

axis, the helix fixed end supported at the plate to extend the helix axis orthogonally to the plate, the helix free end adapted to penetrate through the serosa and the helix adapted to advance into the muscularis externa upon rotation of the helix until the plate is drawn against the serosa.

3. The gastrointestinal lead of Claim 2, wherein the helix has an axial length enabling a depth of penetration from the plate in the range of 1 mm to 15 mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the stomach wall to ensure that the helix free end does not extend substantially through the stomach wall.

4. The gastrointestinal lead of Claim 2, wherein the stimulation/sense electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

5. The gastrointestinal lead of Claim 2, wherein:

the helix is formed of a conductive electrode material; and

the helix fixed end is electrically coupled to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least a portion of the helix that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

6. The gastrointestinal lead of Claim 2, wherein:

the helix is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the helix;

the helix fixed end is electrically coupled to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least an uninsulated second portion of the helix that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

7. The gastrointestinal lead of Claim 2, wherein the helix fixed end is fixedly attached to the plate, and the electrode head is shaped to be engaged by a fixation tool that is manipulated to rotate the electrode head and helix.

8. The gastrointestinal lead of Claim 7, wherein:

the elongated lead body encloses a stylet lumen extending through a lead body trunk and at least a second lead body leg into a second electrode head located at the distal end of the second lead body leg; and

the second electrode head comprises:

a helix comprising one or more coil turn extending from a helix fixed end and a helix free end and having a helix axis; and

a rotatable mechanism fitted into the electrode head and attached to the helix fixed end to extend the helix axis orthogonally to the plate, the rotatable mechanism adapted to be engaged by a stylet advanced through the stylet lumen, whereby the rotatable mechanism is rotated by the stylet to rotate the helix and advance the helix free end through the serosa and into the muscularis externa until the plate is drawn against the serosa.

9. The gastrointestinal lead of Claim 2, wherein:

the elongated lead body encloses a stylet lumen extending through a lead body trunk and at least one lead body leg to the electrode head located at the distal end of the lead body leg supporting the helix; and

the electrode head comprises a rotatable mechanism fitted into the electrode head and attached to the helix fixed end to extend the helix axis orthogonally to the plate, the rotatable mechanism adapted to be engaged by a stylet advanced through the stylet lumen, whereby the rotatable mechanism is

rotated by the stylet to rotate the helix and advance the helix free end through the serosa and into the muscularis externa until the plate is drawn against the serosa.

10. The gastrointestinal lead of Claim 2, wherein another active fixation mechanism of the plurality of active fixation mechanisms comprises a hook comprising a hook shaft extending from a hook fixed end attached to an electrode head to a hook free end spaced from the plate, a sharpened tip and barb formed at the hook free adapted to penetrate through the serosa and to advance into the muscularis externa when insertion force is applied to the electrode head until the plate is drawn against the serosa, whereupon advancement of the hook free end is halted and the barb engages the muscularis externa to inhibit retraction of the hook.

11. The gastrointestinal lead of Claim 1, wherein at least one active fixation mechanism comprises a hook comprising a hook shaft extending from a hook fixed end attached to an electrode head to a hook free end spaced from the plate, a sharpened tip and barb formed at the hook free adapted to penetrate through the serosa and to advance into the muscularis externa when insertion force is applied to the electrode head until the plate is drawn against the serosa, whereupon advancement of the hook free end is halted and the barb engages the muscularis externa to inhibit retraction of the hook.

12. The gastrointestinal lead of Claim 11, wherein the stimulation/sense electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

13. The gastrointestinal lead of Claim 11, wherein:

the hook is formed of a conductive electrode material; and

the hook fixed end is attached to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least a portion of the hook that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

14. The gastrointestinal lead of Claim 11, wherein:

the hook is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the hook;

the hook fixed end is attached to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least an uninsulated second portion of the hook that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

15. The gastrointestinal lead of Claim 14, wherein the plate is substantially planar and the hook shaft comprises a first portion extending from the hook fixed end at a first predetermined angle away from the plate and a second portion extending to the hook free end at a second predetermined angle.

16. The gastrointestinal lead of Claim 11, wherein the plate is substantially planar and the hook shaft comprises a first portion and a second portion joined at a bend, the first portion extending from the hook fixed end to the bend at a first predetermined angle away from the plate and a second portion extending from the bend to the hook free end at a second predetermined angle selected to locate the hook free end further away from the plate than the bend.

17. The gastrointestinal lead of Claim 11, wherein the plate is substantially planar and the hook shaft comprises a first portion and a second portion joined at a bend, the first portion extending from the hook fixed end to the bend at a first predetermined angle away from the plate and a second portion extending from the bend to the hook free end at a second predetermined angle selected to locate the hook free end closer to the plate than the bend.

18. The gastrointestinal lead of Claim 11, wherein the plate is substantially planar and the hook shaft comprises a first portion extending from the hook fixed end at a first predetermined angle away from the plate and a second portion extending to the hook free end at a second predetermined angle.

19. The gastrointestinal lead of Claim 11, wherein the electrode head is shaped to be engaged by a fixation tool that is manipulated to apply the insertion force to advance the hook free end through the serosa and into the muscularis externa.

20. The gastrointestinal lead of Claim 11, wherein the hook free end is distanced from the plate enabling a depth of penetration from the plate in the range of 1 mm to 15 mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the stomach wall to ensure that the helix free end does not extend substantially through the stomach wall.

21. The gastrointestinal lead of Claim 1, wherein at least one electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

22. The gastrointestinal lead of Claim 1, wherein:

at least one active fixation mechanism is formed of a conductive electrode material; and

the active fixation mechanism is electrically coupled to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least a portion of the active fixation mechanism that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

23. The gastrointestinal lead of Claim 1, wherein:

at least one active fixation mechanism is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the active fixation mechanism;

the active fixation mechanism is electrically coupled to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least an uninsulated second portion of the active fixation mechanism that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

24. The gastrointestinal lead of Claim 1, wherein:

the elongated lead body encloses a stylet lumen extending through a lead body trunk and at least one lead body leg to an electrode head located at the distal end of the lead body leg;

at least one fixation mechanism comprises a helix comprising one or more coil turn extending from a helix fixed end and a helix free end and having a helix axis; and

the electrode head comprises a rotatable mechanism fitted into the electrode head and attached to the helix fixed end to extend the helix axis orthogonally to the plate, the rotatable mechanism adapted to be engaged by a stylet advanced through the stylet lumen, whereby the rotatable mechanism is rotated by the stylet to rotate the helix and advance the helix free end through the serosa and into the muscularis externa until the plate is drawn against the serosa.

25. The gastrointestinal lead of Claim 1, wherein:

at least one fixation mechanism comprises a helix comprising one or more coil turn extending from a helix fixed end and a helix free end and having a helix axis;

the elongated lead body encloses a conductor lumen extending through a lead body trunk and at least one lead body leg to the electrode head located at the distal end of the lead body leg supporting the helix; and

the lead conductor extends from a lead connector element through the conductor lumen and to the helix fixed end,

whereby rotation of the lead connector element with respect to the lead connector assembly rotates the lead conductor and helix attached thereto with respect to the plate to advance the helix free end through the serosa and into the muscularis externa until the plate is drawn against the serosa.

26. The gastrointestinal lead of Claim 1, wherein the plurality of active fixation mechanisms each comprise a hook comprising a hook shaft extending from a hook fixed end attached to an electrode head to a hook free end spaced from the plate, a sharpened tip and barb formed at the hook free adapted to penetrate through the serosa and to advance into the muscularis externa when insertion force is applied to the electrode head until the plate is drawn against the serosa, whereupon advancement of the hook free end is halted and the barb engages the muscularis externa to inhibit retraction of the hook.

27. The gastrointestinal lead of Claim 1, wherein an anti-inflammatory material selected from the group consisting of steroids, anti-bacterial agents, baclofen, dexamethasone sodium phosphate or beclomethasone phosphate is incorporated into the electrode head or fixation mechanism.

28. The gastrointestinal lead of Claim 1, wherein the plurality of lead body legs are permanently connected to the common lead body at the junction.

29. The gastrointestinal lead of Claim 1, wherein the plurality of lead body legs are removably connected to the common lead body at the junction.

30. A method of providing gastrointestinal sensing and/or stimulation through a gastrointestinal lead and a gastrointestinal stimulator comprising:

providing an elongated gastrointestinal lead body comprising a common lead body trunk extending from a connector assembly at a lead body proximal end comprising a plurality of connector elements of a lead connector assembly to a junction with a plurality of lead body legs that extend from the junction to a like plurality of lead body leg distal ends, an electrode head formed at each lead body leg distal end having a plate and supporting at least one stimulation/sense electrode and an active fixation mechanism, whereby a plurality of active fixation attachment mechanisms are supported by a plurality of electrode heads, and a plurality of lead conductors enclosed within the lead body, each lead conductor extending between a stimulation/sense electrode through a lead body leg and the lead body trunk to a proximal connector element of the connector assembly;

determining first and second gastrointestinal implantation sites optimally spaced apart for stimulation and/or sensing;

extending a first electrode head supporting a first active fixation mechanism to a first gastrointestinal implantation site;

deploying the first active fixation mechanism extending away from the plate of the electrode head and penetrating through the serosa and into the muscularis externa to draw the plate against the serosa and operatively contact the stimulation/sense electrode with the GI tract wall, whereby the plate inhibits further advancement of the active fixation mechanism and perforation of the GI tract wall and the active fixation mechanism inhibits dislodgement of the stimulation/sense electrode from operative contact with the GI tract wall;

extending a second electrode head supporting a second active fixation mechanism to a second gastrointestinal implantation site spaced from;

deploying the second active fixation mechanism extending away from the plate of the electrode head and penetrating through the serosa and into the muscularis externa to draw the plate against the serosa and operatively contact the stimulation/sense electrode with the GI tract wall, whereby the plate inhibits further

advancement of the active fixation mechanism and perforation of the GI tract wall and the active fixation mechanism inhibits dislodgement of the stimulation/sense electrode from operative contact with the GI tract wall;

coupling the lead connector assembly to a gastrointestinal stimulator connector assembly of an implantable or external gastrointestinal stimulator to conduct electrical stimulation from the implantable or external gastrointestinal stimulator between the first and second sites of the GI tract and to conduct electrical signals of the GI tract from the first and second sites to the implantable or external gastrointestinal stimulator.

31. The method of Claim 30, wherein;

the first active fixation mechanism comprises a helix comprising one or more coil turn extending from a helix fixed end and a helix free end and having a helix axis, the helix fixed end supported at the plate to extend the helix axis orthogonally to the plate; and

the deploying step comprises

pressing the helix free end through the serosa: and

rotating the helix to advance the helix into the muscularis externa until the plate is drawn against the serosa.

32 The method of Claim 31, wherein the helix has an axial length enabling a depth of penetration from the plate in the range of 1 mm to 15 mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the stomach wall to ensure that the helix free end does not extend substantially through the stomach wall.

33 The method of Claim 31, wherein the stimulation/sense electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

34 The method of Claim 31, wherein:

the helix is formed of a conductive electrode material; and

the helix fixed end is electrically coupled to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least a portion of the helix that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

35 The method of Claim 31, wherein:

the helix is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the helix;

the helix fixed end is electrically coupled to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least an uninsulated second portion of the helix that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

36 The method of Claim 31, wherein the helix fixed end is fixedly attached to the plate, and the rotating step comprises:

engaging the electrode head by a fixation tool; and

rotating the fixation tool to rotate the lead body, the electrode head and the helix to advance the helix substantially into the muscularis externa until the plate is drawn against the serosa.

37. The method of Claim 31, wherein the rotating step comprises:

engaging the helix by a fixation tool; and

rotating the fixation tool to rotate the helix with respect to the lead body and the electrode head to advance the helix substantially into the muscularis externa until the plate is drawn against the serosa.

38. The method of Claim 31, wherein:

the elongated lead body encloses a conductor lumen extending through the lead body trunk and the first lead body leg to the first electrode head located at the distal end of the first lead body leg supporting the helix;

the lead conductor extends from a lead connector element through the conductor lumen and to the helix fixed end, and

the rotating step comprises rotating the lead connector element with respect to the lead connector assembly to rotate the helix attached thereto with respect to the plate to advance the helix free end through the serosa and substantially into the muscularis externa until the plate is drawn against the serosa.

39. The method of Claim 31, wherein:

the first electrode head encloses a rotatable mechanism for supporting the helix fixed end;

the elongated lead body encloses a stylet lumen extending through the lead body trunk and the first lead body leg to the first electrode head located at the distal end of the first lead body leg supporting the helix; and

the rotating step comprises:

inserting a stylet wire having through the stylet lumen to engage the rotatable mechanism; and

rotating the lead stylet with respect to the lead connector assembly to rotate the helix attached to the rotatable mechanism with respect to the plate to advance the helix free end through the serosa and substantially into the muscularis externa until the plate is drawn against the serosa.

40. The method of Claim 31, wherein:

the second active fixation mechanism comprises a hook comprising a hook shaft extending from a hook fixed end attached to the second electrode head to a hook free end spaced from the plate of the second electrode head terminating in a sharpened tip and barb; and

the second deploying step comprises

engaging the second electrode head by a second fixation tool; and

applying force through the second fixation tool to press the hook free end through the serosa and lodge the hook substantially into the muscularis externa until the plate is drawn against the serosa.

41. The method of Claim 30, wherein;

the first active fixation mechanism comprises a first helix comprising one or more coil turn extending from a first helix fixed end and a first helix free end and having a first helix axis, the first helix fixed end supported at and fixed to the plate to extend the first helix axis orthogonally to the plate;

the second active fixation mechanism comprises a second helix comprising one or more coil turn extending from a second helix fixed end and a second helix free end and having a second helix axis, the second helix fixed end supported by a rotatable mechanism of the electrode head to extend the second helix axis orthogonally to the plate;

the first deploying step comprises:

engaging the first electrode head by a first fixation tool;

pressing the first helix free end through the serosa: and

rotating the first fixation tool to rotate the lead body, the electrode head and the first helix to advance the first helix substantially into the muscularis externa until the plate is drawn against the serosa;

wherein the second deploying step comprises:

engaging the second helix by a second fixation tool;

pressing the second helix free end through the serosa: and

rotating the second fixation tool to rotate the second helix with respect to the lead body and the electrode head to advance the second helix substantially into the muscularis externa until the plate is drawn against the serosa.

42. The method of Claim 30, wherein:

at least one of the first and second active fixation mechanisms comprises a hook comprising a hook shaft extending from a hook fixed end attached to the electrode head to a hook free end spaced from the plate of the electrode head terminating in a sharpened tip and barb; and

the step of deploying the hook comprises

engaging the electrode head by a hook fixation tool; and

applying force through the hook fixation tool to press the hook free end through the serosa and lodge the hook substantially into the muscularis externa until the plate is drawn against the serosa.

43. The method of Claim 42, wherein the stimulation/sense electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

44. The method of Claim 42, wherein:

the hook is formed of a conductive electrode material; and

the hook fixed end is attached to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least a portion of the hook that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

45. The method of Claim 42, wherein:

the hook is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the hook;

the hook fixed end is attached to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least an uninsulated second portion of the hook that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

46. The method of Claim 42, wherein the plate is substantially planar and the hook shaft comprises a first portion extending from the hook fixed end at a first predetermined angle away from the plate and a second portion extending to the hook free end at a second predetermined angle.

47. The method of Claim 42, wherein the plate is substantially planar and the hook shaft comprises a first portion and a second portion joined at a bend, the first portion extending from the hook fixed end to the bend at a first predetermined angle away from the plate and a second portion extending from the bend to the hook free end at a second predetermined angle selected to locate the hook free end further away from the plate than the bend.

48. The method of Claim 42, wherein the plate is substantially planar and the hook shaft comprises a first portion and a second portion joined at a bend, the first portion extending from the hook fixed end to the bend at a first predetermined angle away from the plate and a second portion extending from the bend to the hook free end at a second predetermined angle selected to locate the hook free end closer to the plate than the bend.

49. The method of Claim 42, wherein the plate is substantially planar and the hook shaft comprises a first portion extending from the hook fixed end at a first predetermined angle away from the plate and a second portion extending to the hook free end at a second predetermined angle.

50. The method of Claim 42, wherein the electrode head is shaped to be engaged by the hook fixation tool that is manipulated to apply the insertion force to advance the hook free end through the serosa and into the muscularis externa.

51. The method of Claim 42, wherein the hook free end is distanced from the plate enabling a depth of penetration from the plate in the range of 1 mm to 15

mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the stomach wall to ensure that the helix free end does not extend substantially through the stomach wall.

52. The method of Claim 30, wherein at least one electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

53. The method of Claim 30, wherein:

at least one active fixation mechanism is formed of a conductive electrode material; and

the active fixation mechanism is electrically coupled to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least a portion of the active fixation mechanism that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

54. The method of Claim 30, wherein:

at least one active fixation mechanism is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the active fixation mechanism;

the active fixation mechanism is electrically coupled to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least an uninsulated second portion of the active fixation mechanism that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

55. The method of Claim 30, wherein the plurality of active fixation mechanisms each comprise a hook comprising a hook shaft extending from a hook fixed end attached to an electrode head to a hook free end spaced from the plate, a sharpened tip and barb formed at the hook free adapted to penetrate through the serosa and to advance into the muscularis externa when insertion force is applied to the electrode head until the plate is drawn against the serosa, whereupon advancement of the hook free end is halted and the barb engages the muscularis externa to inhibit retraction of the hook.

56. The method of Claim 30, wherein an anti-inflammatory material selected from the group consisting of steroids, anti-bacterial agents, baclofen, dexamethasone sodium phosphate or beclomethasone phosphate is incorporated into the electrode head or fixation mechanism.

57. The method of Claim 30, wherein the plurality of lead body legs are permanently connected to the common lead body at the junction.

58. The method of Claim 30, wherein the plurality of lead body legs are removably connected to the common lead body at the junction.

59. A system providing gastrointestinal sensing and/or stimulation comprising:

a gastrointestinal lead comprising an elongated gastrointestinal lead body comprising a common lead body trunk extending from a connector assembly at a lead body proximal end comprising a plurality of connector elements of a lead connector assembly to a junction with a plurality of lead body legs that extend from the junction to a like plurality of lead body leg distal ends, an electrode head formed at each lead body leg distal end having a plate and supporting at least one stimulation/sense electrode and an active fixation mechanism, whereby a plurality of active fixation attachment mechanisms are supported by a plurality of electrode

heads, and a plurality of lead conductors enclosed within the lead body, each lead conductor extending between a stimulation/sense electrode through a lead body leg and the lead body trunk to a proximal connector element of the connector assembly;

first deploying means for deploying the first active fixation mechanism extending away from the plate of the electrode head and penetrating through the serosa and into the muscularis externa to draw the plate against the serosa and operatively contact the stimulation/sense electrode with the GI tract wall, whereby the plate inhibits further advancement of the active fixation mechanism and perforation of the GI tract wall and the active fixation mechanism inhibits dislodgement of the stimulation/sense electrode from operative contact with the GI tract wall;

second deploying means for deploying the second active fixation mechanism extending away from the plate of the electrode head and penetrating through the serosa and into the muscularis externa to draw the plate against the serosa and operatively contact the stimulation/sense electrode with the GI tract wall, whereby the plate inhibits further advancement of the active fixation mechanism and perforation of the GI tract wall and the active fixation mechanism inhibits dislodgement of the stimulation/sense electrode from operative contact with the GI tract wall; and

an implantable or external gastrointestinal stimulator having a gastrointestinal stimulator connector coupled with the lead connector assembly to conduct electrical stimulation from the implantable or external gastrointestinal stimulator between the first and second sites of the GI tract and to conduct electrical signals of the GI tract from the first and second sites to the implantable or external gastrointestinal stimulator.

60. The system of Claim 59, wherein;

the first active fixation mechanism comprises a helix comprising one or more coil turn extending from a helix fixed end and a helix free end and having a helix

axis, the helix fixed end supported at the plate to extend the helix axis orthogonally to the plate; and

the first deploying means comprises

means for pressing the helix free end through the serosa: and

means for rotating the helix to advance the helix into the muscularis externa until the plate is drawn against the serosa.

61 The system of Claim 60, wherein the helix has an axial length enabling a depth of penetration from the plate in the range of 1 mm to 15 mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the stomach wall to ensure that the helix free end does not extend substantially through the stomach wall.

62 The system of Claim 60, wherein the stimulation/sense electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

63 The system of Claim 60, wherein:

the helix is formed of a conductive electrode material; and

the helix fixed end is electrically coupled to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least a portion of the helix that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

64 The system of Claim 60, wherein:

the helix is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the helix;

the helix fixed end is electrically coupled to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least an uninsulated second portion of the helix that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

65 The system of Claim 60, wherein the helix fixed end is fixedly attached to the plate, and the rotating means comprises a first fixation tool that engages the electrode head and is rotatable to rotate the lead body, the electrode head and the helix to advance the helix substantially into the muscularis externa until the plate is drawn against the serosa.

66. The system of Claim 60, wherein the rotating means comprises a first fixation tool that engages the helix and rotates the helix with respect to the lead body and the electrode head to advance the helix substantially into the muscularis externa until the plate is drawn against the serosa.

67. The system of Claim 60, wherein:

the elongated lead body encloses a conductor lumen extending through the lead body trunk and the first lead body leg to the first electrode head located at the distal end of the first lead body leg supporting the helix;

the lead conductor extends from a lead connector element through the conductor lumen and to the helix fixed end, whereby the lead connector element and lead conductor attached thereto are rotatable with respect to the lead connector assembly to rotate the helix attached thereto with respect to the plate to advance the helix free end through the serosa and substantially into the muscularis externa until the plate is drawn against the serosa.

68. The system of Claim 60, wherein:

the first electrode head encloses a rotatable mechanism for supporting the helix fixed end;

the elongated lead body encloses a stylet lumen extending through the lead body trunk and the first lead body leg to the first electrode head located at the distal end of the first lead body leg supporting the helix; and

the rotating means comprises a stylet having a stylet wire extendable through the stylet lumen to engage the rotatable mechanism to rotate the helix attached to the rotatable mechanism with respect to the plate to advance the helix free end through the serosa and substantially into the muscularis externa until the plate is drawn against the serosa.

69. The system of Claim 60, wherein:

the second active fixation mechanism comprises a hook comprising a hook shaft extending from a hook fixed end attached to the second electrode head to a hook free end spaced from the plate of the second electrode head terminating in a sharpened tip and barb; and

the second deploying means comprises a second fixation tool adapted to engage the second electrode head to apply force through the second fixation tool to press the hook free end through the serosa and lodge the hook substantially into the muscularis externa until the plate is drawn against the serosa.

70. The system of Claim 59, wherein;

the first active fixation mechanism comprises a first helix comprising one or more coil turn extending from a first helix fixed end and a first helix free end and having a first helix axis, the first helix fixed end supported at and fixed to the plate to extend the first helix axis orthogonally to the plate;

the first deploying means comprises a first fixation tool for engaging the first electrode head, pressing the first helix free end through the serosa, and rotating the lead body, the electrode head, and the first helix to advance the first helix substantially into the muscularis externa until the plate is drawn against the serosa;

the second active fixation mechanism comprises a second helix comprising one or more coil turn extending from a second helix fixed end and a second helix

free end and having a second helix axis, the second helix fixed end supported by a rotatable mechanism of the electrode head to extend the second helix axis orthogonally to the plate; and

the second deploying means comprises a second fixation tool for engaging the second helix, pressing the second helix free end through the serosa, and rotating the second helix to advance the first helix substantially into the muscularis externa until the plate is drawn against the serosa.

71. The system of Claim 59, wherein:

at least one of the first and second active fixation mechanisms comprises a hook comprising a hook shaft extending from a hook fixed end attached to the electrode head to a hook free end spaced from the plate of the electrode head terminating in a sharpened tip and barb; and

the deploying means comprises a hook fixation tool adapted to engage the electrode head to apply force through the second fixation tool to press the hook free end through the serosa and lodge the hook substantially into the muscularis externa until the plate is drawn against the serosa

the step of deploying the hook comprises

engaging the electrode head by a hook fixation tool; and

applying force through the hook fixation tool to press the hook free end through the serosa and lodge the hook substantially into the muscularis externa until the plate is drawn against the serosa.

72. The system of Claim 71, wherein the stimulation/sense electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

73. The system of Claim 71, wherein:

the hook is formed of a conductive electrode material; and

the hook fixed end is attached to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least a portion of the hook that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

74. The system of Claim 71, wherein the plate is substantially planar and the hook shaft comprises a first portion extending from the hook fixed end at a first predetermined angle away from the plate and a second portion extending to the hook free end at a second predetermined angle.

75. The system of Claim 71, wherein:

the hook is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the hook;

the hook fixed end is attached to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least an uninsulated second portion of the hook that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

76. The system of Claim 71, wherein the plate is substantially planar and the hook shaft comprises a first portion and a second portion joined at a bend, the first portion extending from the hook fixed end to the bend at a first predetermined angle away from the plate and a second portion extending from the bend to the hook free end at a second predetermined angle selected to locate the hook free end further away from the plate than the bend.

77. The system of Claim 71, wherein the plate is substantially planar and the hook shaft comprises a first portion and a second portion joined at a bend, the first portion extending from the hook fixed end to the bend at a first predetermined angle away from the plate and a second portion extending from the bend to the hook free end at a second predetermined angle selected to locate the hook free end closer to the plate than the bend.

78. The system of Claim 71, wherein the plate is substantially planar and the hook shaft comprises a first portion extending from the hook fixed end at a first predetermined angle away from the plate and a second portion extending to the hook free end at a second predetermined angle.

79. The system of Claim 71, wherein the electrode head is shaped to be engaged by the hook fixation tool that is manipulated to apply the insertion force to advance the hook free end through the serosa and into the muscularis externa.

80. The system of Claim 71, wherein the hook free end is distanced from the plate enabling a depth of penetration from the plate in the range of 1 mm to 15 mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the stomach wall to ensure that the helix free end does not extend substantially through the stomach wall.

81. The system of Claim 59, wherein at least one electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

82. The system of Claim 59, wherein:

at least one active fixation mechanism is formed of a conductive electrode material; and

the active fixation mechanism is electrically coupled to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least a portion of the active fixation mechanism that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

83. The system of Claim 59, wherein:

at least one active fixation mechanism is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the active fixation mechanism;

the active fixation mechanism is electrically coupled to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least an uninsulated second portion of the active fixation mechanism that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

84. The system of Claim 59, wherein the plurality of active fixation mechanisms each comprise a hook comprising a hook shaft extending from a hook fixed end attached to an electrode head to a hook free end spaced from the plate, a sharpened tip and barb formed at the hook free adapted to penetrate through the serosa and to advance into the muscularis externa when insertion force is applied to the electrode head until the plate is drawn against the serosa, whereupon advancement of the hook free end is halted and the barb engages the muscularis externa to inhibit retraction of the hook.

85. The system of Claim 59, wherein an anti-inflammatory material selected from the group consisting of steroids, anti-bacterial agents, baclofen, dexamethasone sodium phosphate or beclomethasone phosphate is incorporated into the electrode head or fixation mechanism.

86. The system of Claim 59, wherein the plurality of lead body legs are permanently connected to the common lead body at the junction.

87. The system of Claim 59, wherein the plurality of lead body legs are removably connected to the common lead body at the junction.